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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,145	12/14/2001	John Shanklin	BSA 02-04	2640

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EXAMINER

SAIDHA, TEKCHAND

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/09/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/017145

Applicant(s)

Shanklin et al.

Examiner

T. Swidha

Group Art Unit

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—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE — 3 — MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 8/11/03
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1, 3-5 & 60 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 3-5 & 60 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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Final Rejection

1. Applicants' Amendment and Declaration filed 8.11.03 (Paper Nos. 9 & 10) in response to Office Action dated 03.02.03, is acknowledged. As per the amendment claims 2 & 6-59 are canceled.
2. Claims 1, 3-5 & 60 are pending and under consideration in this Office Action.
3. Any objection or rejection of record which is not expressly repeated in this Office Action has been overcome by Applicant's response and withdrawn.
4. Applicant's arguments filed as per the amendment cited above have been fully considered but they are not deemed to be persuasive. The reasons are discussed following the rejection(s).

5. ***Oath/Declaration***

The oath or declaration is defective because : the oath is not signed by the newly added inventor 'Edward J. Whittle'. A new oath/declaration is required.

Applicants in responding to prior detailed Office Action have indicated that a new Oath or declaration by the new inventor is in preparation for submission.

This requirement is repeated as a reminder to the Applicants as well for the records.

6. The amendment filed 8.11.03 (Paper No. 9) is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

Claim 1, line 3, recites '**two or more** amino acid substitution', for which there is no basis in the specification.

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Applicant is required to cancel the new matter in the reply to this Office Action.

7. ***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1, 3-5 & 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Cahoon et al. [PNAS 94 : 4872-4877, May 1997, Reference 1]. Cahoon et al. teach castor mutants or modified Δ^9 -18:0-ACP desaturase and the crystallographic model of the active sites and variants or mutants. Characterization of specific mutants at positions 114, 117, 118, 179, 181 & 188 are also taught (see the entire document, especially abstract, Fig. 3, and page 4875-column 2). The reference also teaches specific positions which can be replaced by any amino acid or which can be used for making two or more amino acid substitutions in the castor Δ^9 -18:0-ACP desaturase and having increased activity towards fatty acids having fewer than 18 carbon [see column 5, lines 50-60] All the elements of the claims been taught, the reference anticipates the claims.

8. Claims 1, 3-5 & 60 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S.P. 5,705,391 (Cahoon et al., Jan 6, 1998, Reference 2). Cahoon et al. teach mutants or modified Δ^9 -18:0-ACP desaturase (see column 4, last paragraph) at the identified contact residues M114, L115,

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T117, L118, G188 & F189, and how these specific positions can be replaced by any other amino acid or which can be used for making two or more amino acid substitutions in the castor Δ^9 -18:0-ACP desaturase and having increased activity towards fatty acids having fewer than 18 carbon. The reference anticipates the claims.

9. Claims 1, 3-5 & 60 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S.P. 5,888,790 (Cahoon et al., filed May 9, 1997, Reference 3). Cahoon et al. teach mutants or modified Δ^9 -18:0-ACP desaturase (see claims 10-12) at the identified contact residues M114, L115, T117, L118, G188 & F189, and how these specific positions can be replaced by any other amino acid or which can be used for making two or more amino acid substitutions in the castor Δ^9 -18:0-ACP desaturase and having increased activity towards fatty acids having fewer than 18 carbon. The claims are drawn to any amino acid substitution at the positions indicated and encompass the specific amino acid substitution(s) claimed. All the limitations being taught, the reference anticipates the claims.

Applicants' Arguments :

Applicants arguments with respect to rejections in items 7-9, lay emphasis upon : (1) that single replacement is not claimed in the present invention; (2) references 1 and 3 teach specific double mutants [leu118phe; pro179ile in castor Δ^9 -18:0-ACP desaturase] which replacements are not being claimed; References 1 & 3 do not provide guidance as to how to arrive at any of the substitutions of the present invention ?; (3) claims of the present invention, as herein amended, are drawn to mutants of castor Δ^9 -18:0-ACP desaturase having increased activity towards fatty acids having fewer than 18 carbon, said mutant having two or more specifically identified amino acid

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substitutions, and specification of the present invention provides one of skill in the art with all the necessary guidance to practice the invention as claimed; and (4) summarizing the inventors declaration, it is conveyed from the arguments that of the 800 mutants suggested in the reference only one double mutants could be construed as being suggested by the guidance they have found, and that one would be required to prepare 61 double mutants to discover the double mutant suggested in Reference 1.

In response it is realized that applicants are claiming more than two or more replacements which is encompassed by the one or more replacements taught by the reference(s); and that the specific mutants not being claimed is unimportant, because what the references teach are the specific positions which can be replaced by any amino acid or which can be used for making two or more amino acid substitutions in the castor Δ^9 -18:0-ACP desaturase and having increased activity towards fatty acids having fewer than 18 carbon [see for example, U.S.P. '391, column 3-5, column 5, lines 50-60]. Further, the references clearly teach not only the specific positions to be modified within the substrate binding groove, but also provide guidance to one skilled in the art to make and use the invention as claimed irrespective of the time involved to repeat the standard protocol in order to make the desired the specific amino acids substitutions (one or more ; or two or more) at the specific positions taught by each of the references.

10. ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment

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by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2-5 & 60 are rejected under the judicially created doctrine of double patenting over claims 7-20 of U. S. Patent No. 5,888,790, since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: Cahoon et al. teach mutants or modified Δ^9 -18:0-ACP desaturase (see claims 10-12) at the identified contact residues M114, L115, T117, L118, G188 & F189, and how these specific positions can be replaced by any other amino acid or which can be used for making two or more amino acid substitutions in the castor Δ^9 -18:0-ACP desaturase and having increased activity towards fatty acids having fewer than 18 carbon. The claims are drawn to a mutant castor Δ^9 -18:0-ACP desaturase having two or more amino acid substitutions [this being encompassed by the one or more amino acid substitution language in the patent] at the positions indicated and encompass the specific amino acid substitution(s) claimed. All the limitations being taught, the reference anticipates the claims.

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Applicants' main concern regarding the claims as amended is addressed in the arguments presented following items 7-9, as well as in the revised text of the rejection for double patenting (see above).

11. ***Claim Rejections - 35 USC § 112*** (second paragraph)

Claims 1, 3-5 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1, line 2, recites 'substantial increase'. The phrase "substantial increase" in claim 1 is a relative term which renders the claim indefinite. The term "substantial increase" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Using a positive expression clearly defining the extent of increase, will overcome this rejection.

Claims 3-5 are included in the rejection for failing to correct the defect present in the base claim(s).

12. Claims provisionally rejected under the judicially created doctrine of double patenting over claims 28-42 of copending Application No. 09/988929, is hereby withdrawn because of diverse subject matter being prosecuted in the copending application and which has now been allowed..

13. No claim is allowed.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha (Ph.D.) whose telephone number is (703) 305-6595. The examiner can normally be reached on Monday-Friday from 8:15 am to 4:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group in the Technology Center is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Tekchand Saidha

Primary Examiner, Art Unit 1652

October 6, 2003